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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/051,253	01/18/2002	Robert L. Stout	32265	7968

7590 11/03/2004

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EXAMINER	
BROWN, TIMOTHY M	

ART UNIT	PAPER NUMBER
1648	

DATE MAILED: 11/03/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/051,253	STOUT, ROBERT L.	
	Examiner	Art Unit	
	Tim Brown	1648	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on 02 June 2004.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) 1-30 is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) 1-30 is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

This Final Office Action is responsive to Applicant's amendment submitted June 2, 2004.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-30 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which Applicant regards as the invention.

Claim 1 is confusing as it is unclear what process is being claimed. It is unclear whether "determining an optical density" is a part of, or is in addition to, "performing an HCV antibody-based assay." It is unclear whether "using said determined optical density ..." is intended to represent an active process step or is intended to be language correlating the result of the final, "determining," step with the preamble.

Claim 2 is confusing because it recites "said optical density determining step occurring only on said samples testing positive said HCV antibody-based assay" since the only "antibody based assays" disclosed also involve determining optical density as a part of an immunoassay that uses HCV antigens to determine the presence of HCV antibodies in samples.

Claim 12 is indefinite because the only process step recited is that of "measuring the optical density of said fluid sample." Since a method claim is defined by process steps, no meaningful method or assay is represented by merely measuring optical

density of a fluid sample. Claims 15-18 are indefinite because each recites a particular optical density value ("less than 1 .0"; " less than 2.35"; greater than about 2.35"; and "greater than 3.0"; respectively). An optical density value standing alone is meaningless, since optical density values obtained in the course of performing assays depend on, *inter alia*, wave length settings and sample dilutions.

Claim 19 is indefinite because it recites "contacting said fluid sample with HCV antibodies to form a solution." It is not clear what method step Applicant intends to claim. Relying on the specification to help interpret the claim, it is noted that the specification teaches, in Example 1, performing a second test using HCV antigen to detect anti-Hcv antibodies on samples that had tested positive for anti-Hcv antibodies in a first test. It is possible that Applicant intended "contacting ... HCV antigen" rather than "HCV antibodies."

Claims 22-25, like claims 15-18, are indefinite because each recites a particular optical density value ("less than 1 .0"; " less than 2.35"; greater than about 2.35"; and "greater than 3.0"; respectively). An optical density value standing alone is meaningless, since optical density values obtained in the course of performing assays can only be interpreted by one with knowledge of such pertinent information as sample dilutions or the wavelength settings that are determined by the color of the product formed.

Claim 26 is confusing as it is unclear what process is being claimed. It is unclear whether "measuring the optical density" is a pad of, or is in addition to, "performing an antibody-based assay." Further, claim 26 recites in the preamble "A method of testing for chronic HCV infection ..." but does not recite any ianguage that would correlate the

results of the final "measuring' step with the preamble. Lacking such language, the claim is incomplete.

While the claims are indefinite as discussed above, to the extent that at least some of the claims are understood generally to be drawn to a method of correlating a relatively high amount of anti-Hcv antibody in a patient sample to the probability that the patient has chronic HCV, the following rejection over prior art is offered.

Claim Rejections - 35 USC § 103

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claims 1, 4-11, 12-14, and 26-30 are rejected under 35 U.S.C. 103(a) as being unpatentable over WO 00/26673, Scheffel et aI..

Scheffel et al. disclose the correlation of sustained high titers of anti-Hcv antibody to HCV E2 antigen with chronic HCV infection (see, e.g., page 11 , lines 1-9). Samples were initially tested for the presence of anti-Hcv antibody by commercially available EIA (see page 17, Assay, lines 22-27) and samples testing positive were then further tested to determine the levels, or titers, of anti-Hcv antibodies (see page 17, Assay, lines 14-22, Table 1, column headed "PEAK E2 UNITS). Scheffel et al. teach obtaining results of an ELISA using a chromogenic substrate in which the appropriate signal output equates to optical density value of a neat or diluted test sample, and constructing a reference curve from which antibody can be quantified (see page 13, lines 6-22), as well as testing samples from patients with known chronic and self-limiting HCV infections to establish a "cutoff" value so that correlation values can be established

such that one could draw a reasonable conclusion as a patient's HCV status from a single data point (page 12, lines 13-28, e.g.). Scheffel et al. differ from Applicant's claimed method only by disclosing the correlation of the amount of HCV E2 antibodies with chronic infection', however, Applicant's claims recite anti-Hcv antibodies broadly and do not distinguish over the teachings of Scheffel. It would have been obvious to one of skill in the art to detect levels or amounts or titers of anti-Hcv antibodies in patient samples, using methods that employ an optical density reading to indicate the antibody levels, amounts, or titers, and to correlate a relatively high amount of anti-HCV antibodies with a high likelihood of the presence of chronic HCV, and a relatively low amount of anti-HCV antibodies with a lower likelihood of chronic HCV, based on the teachings of Scheffel et al. regarding anti-HCV E2.

Note that although Scheffel et al. does not expressly teach determining optical density only on samples that are positive of HCV antibodies, it would have been obvious to one of ordinary skill in the art, to include this step. Scheffel et al. is drawn to detecting chronic HCV infection. Therefore, on of ordinary skill would have been motivated to exclude sampling individuals who are free of HCV infection. Performing an HCV antibody assay is one obvious means of accomplishing this. Therefore, one of ordinary skill in the art would have been motivated to use an antibody-based assay to exclude non-HCV infected individuals from Scheffel et al.'s method of detecting chronic HCV in order to provide a useful patient sample.

Claims 15-18, and 22-25 are not included in this rejection only because they are so unclear as explained above.

Response to Arguments

The rejection of claims 1-30 under 35 U.S.C. Section 112, second paragraph is maintained. Applicants argue claims 1 and 26 are definite because it requires performing each of four independent steps. While this may be true, it is not clear how each step relates to the claimed method. In particular, it is unclear how "performing an HCV antibody-based assay" contributes to identifying chronic HCV since chronic HCV is being identified by optical density. Note that this rejection may be overcome by amending claim 1 to recite the limitations of claim 2, and canceling claim 2. Note that the rejection of claim 2 as being indefinite is withdrawn in view of Applicant's remarks.

The rejection of claims 3 and 19 is withdrawn in view of Applicant's amendment.

The rejection of claim 12 is maintained. Applicant argues this rejection should be withdrawn because the claim unambiguously requires two distinct steps. The Examiner respectfully submits indefiniteness does not turn on the number of steps in a method. Claim 12 is a method for predicting chronic HCV infection comprising measuring the optical density of a fluid sample from an individual, and correlating the measured optical density with the probability that the individual has chronic HCV. It is unclear how Applicant's correlating step predicts chronic HCV since the method correlates optical density with a value that the method is attempting to predict. Accordingly, the rejection of claim 12 is maintained.

The Examiner notes that the specification shows that Applicant's method predicts chronic HCV by comparing the optical density of a sample, to a standard optical density value from individuals known to have chronic HCV (p. 4, lines 6-15). Thus, Applicant may want to consider amending claim 12 as follows: "correlating said measured optical density with a

predetermined standard optical density value derived from individuals known to have chronic HCV infection."

The rejection of claims 15-18 and 22-25 is maintained. Applicant argues this rejection should be withdrawn because one of ordinary skill in the art would know the scope of the claim because they would be guided by positive and negative controls, and instructions from a commercially available kit. This argument is not persuasive because the claims do not require positive and negative controls or a commercially available kit. Therefore, these limitations do not define the scope of the claim. Because claims 15-18 remain indefinite, their rejection is maintained.

The rejection of claims 1, 4-11, 12-14 and 26-30 under 35 U.S.C. § 103(a) is maintained. Applicant argues the present amendment overcomes the rejection because the prior art (Scheffel et al. WO 00/26673) does not teach an assay that is capable of detecting more than one HCV antibody. The Examiner respectfully submits this amendment does distinguish Applicant's method from the art. First, the amendment does not present an *affirmative step* wherein more than one antibody is detected. Second, the claims do not actually require performing an antibody assay since the probability of chronic HCV infection is based on optical density. Moreover, as mentioned above, the step of performing an antibody-based assay lacks a connection to the other steps. Therefore, requiring that the immunoassay can detect more than one antibody does not distinguish Applicant's method from the art.

Conclusion

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Tim Brown whose telephone number is (571) 272-0773. The examiner can normally be reached on Monday - Friday, 8am - 5pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James Housel can be reached on (571) 272-0902. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Timothy M. Brown
Examiner
Art Unit 1648

tmb

James C. Housel 11/1/04